REMARKS

This Amendment is responsive to the Final Office Action dated July 17, 2008.

Applicant has amended independent claim 1 as requested by Examiner Holmes during the Examiner Interview summarized below. Applicant has also amended dependent claim 9, 31 and 34 to correct minor typographical errors. In addition, Applicant has amended independent claim 29.

Upon entry of the Amendment, claims 1-9, 11-31, and 33-36 would remain pending.

Summary of Examiner Interview

In a telephonic interview initiated by Applicant on September 18, 2008, Applicant's representative, Steven Shumaker, Examiner Rex Holmes, and Examiner George Evanisko discussed the Final Office Action mailed on July 17, 2008. The parties generally discussed the Bourgeois reference cited in the Final Office Action in view of the pending claims.

During the telephonic interview, Examiners Holmes and Evanisko agreed with Applicant's representative that the Bourgeois reference does not describe delivering electrical stimulation when normal gastric activity is detected, wherein the electrical stimulation is configured to disrupt normal gastric activity. In particular, they agreed that the "Y" and "N" in the first block of FIG. 7 of Bourgeois are erroneously swapped, and that one of ordinary skill in the art would appreciate that error upon reviewing the specification.

Examiners Holmes and Evanisko indicated that independent claims 35 and 36 appear to be allowable, pending further analysis of the Bourgeois reference, and suggested amendment of independent claim 1 to more affirmatively recite a delivery of electrical stimulation when normal gastric activity is detected, wherein the stimulation is configured to disrupt normal gastric activity. Examiners Holmes and Evanisko requested that Applicant's file an amendment to this effect, including claim amendments to claim 1 and remarks consistent with the interview.

No exhibits were introduced during the interview.

Allowable Subject Matter

In the Final Office Action, the Examiner indicated that claims 19-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Office Action Summary indicated that claims 19-26 were rejected, contrary to the indication of allowable subject matter in the body of the Final Office Action. It appears that the Examiner may have intended to object to claims 19-26 but inadvertently indicated that the respective claims were rejected in the Office Action Summary. Applicant assumes that claims 19-26 were not rejected in the Final Office Action, but would appreciate clarification of this point.

Claim Rejection Under 35 U.S.C. § 112

In the Final Office Action, the Examiner rejected claim 34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As a basis for the rejection, the Office Action indicated that claim 34 was dependent on a non-existent claim (claim 32).

In this Amendment, Applicant has amended claim 34 to properly depend from claim 29. Applicant submits that claim 34, as amended, meets the requirements of 35 U.S.C. 112, second paragraph. Therefore, withdrawal of the rejection is respectfully requested.

Claim Rejection Under 35 U.S.C. § 102

In the Final Office Action, the Examiner rejected claims 1-5, 7-9, 27-29, 31 and 33-36 under 35 U.S.C. 102(e) as being anticipated by Bourgeois (US 6,216,039).

Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Bourgeois fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claim 1 recites a system for gastric stimulation of a patient comprising sensing electrodes for sensing intrinsic gastric activity from a stomach wall of a patient, and an implantable gastric stimulator coupled to the sensing electrodes, the implantable gastric

stimulator receiving the sensed intrinsic gastric activity and performing an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal, and determining whether to create an electrical stimulation based at least in part upon the classification of the sensed intrinsic gastric activity as normal or abnormal. Per claim 1, the implantable gastric stimulator delivers the electrical stimulation when the sensed intrinsic gastric activity is classified as normal. The system further comprises a plurality of stimulation electrodes configured to convey the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient when the sensed intrinsic gastric activity is classified as normal. Per claim 1, the electrical stimulation is configured to disrupt normal gastric activity of the stomach.

The Final Office Action, with regard to claims 1, 27, 29, 34 and 35, stated that:

> Bourgeois discloses a system for gastric stimulation that utilizes a plurality of sensing electrodes (5) and a plurality of stimulating electrodes (4) placed in the stomach for sensing intrinsic activity (e.g. Fig. 1). Bourgeois further discloses that it classifies the intrinsic activity as normal or abnormal and then stimulates the stomach with different stimulation parameters based on the classification (e.g. Fig. 7, see steps 7-8 and 7-14 which determine if normal waves are occurring and if so provides stimulation therapy at step 7-9).

On this basis, the Final Office Action concluded that Bourgeois anticipates claims 1, 27, 29, 34, and 35.

Applicant respectfully disagrees. For example, Bourgeois fails to teach or disclose the feature of an implantable gastric stimulator creating electrical stimulation when the sensed intrinsic gastric activity is classified as normal. Likewise, Bourgeois does not disclose an implantable gastric stimulator that delivers electrical stimulation when the sensed intrinsic gastric activity is classified as normal, nor a plurality of stimulation electrodes configured to convey the electrical stimulation from the implantable gastric stimulator to the stomach wall. Notably, Bourgeois also fails to teach or disclose electrical stimulation configured to disrupt normal gastric activity of the stomach, as recited by amended claim 1.

In general, Bourgeois describes an apparatus and method for diagnosing and treating irregular gastric rhythms such as bradygastria and tachygastria.[1] As described by Bourgeois, the apparatus includes, *inter alia*, a sensor to sense slow waves and determine whether the slow

[1] Bourgeois, Abstract.

waves are occurring in an irregular or unstable manner.[2] The apparatus further permits the sensed slow waves to be diagnosed as being part of a bradygastria or a tachygastria and, in response, provides appropriate electrical stimulation delivered to the stomach of a patient.[3]

For example, Figure 7 of Bourgeois, cited by the Examiner in the Final Office Action, generally illustrates steps used by such an apparatus to normalize irregular slow waves by sensing slow waves, determining whether the slow waves are outside of a normal slow wave band, and delivering electrical stimulation to normalize the slow waves when they are outside of the normal band.[4] Initially, the rate of sensed slow waves is determined and compared to a range of values that are defined based on a normal slow wave rate (7-2).[5]

In the example shown in FIG. 7 of Bourgeois for treating the stomach, the range of 2.7 to 3.3 beats per minute (bpm) is defined as the normal slow wave rate.[6] If the sensed slow wave rate is outside of the normal range, then steps are taken to characterize the nature of the sensed irregular slow waves, and deliver appropriate electrical stimulation to normalize the slow wave rate based on the characterization. If the sensed slow wave is normal, however, the Bourgeois device continues to monitor the slow-wave (7-2) until the slow wave rate is outside the normal range. In this case, the process proceeds to block 7-3. As was discussed in the above-referenced Examiner Interview, Applicant notes that the "Y" and "N" associated with block 7-2 are clearly reversed, as the text of the Bourgeois patent refers to proceeding to block 7-3 when the answer to the query in block 7-2 is "yes."

As further described by Bourgeois, if the slow rate is determined to be below 2.5 bpm for a specified amount of time, electrical stimulation is delivered that is configured to increase the slow wave rate.[7] Conversely, if the slow wave rate is higher than the normal rate for a specified amount of time, electrical stimulation is delivered that is configured to decrease the slow wave rate.[8]

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[2] *Id.*
[3] *Id.*
[4] *Id.* at Column 8, line 60 to Column 9, line 67; FIG. 7.
[5] *Id.* at col. 9. lines 1-11.
[6] *Id.* at col. 9, lines 3-7.
[7] *See e.g.,* blocks 7-4 to 7-8 of FIG. 7.
[8] *See e.g.,* blocks 7-10 to 7-14 of FIG. 7.

In each case, however, the electrical stimulation (represented by blocks 7-7 and 7-13, respectively) is configured to return the slow wave to a normal rate i.e., to normalize the slow wave rate, when the slow wave rate is determined to be irregular, rather than delivering electrical stimulation configured to disrupt normal gastric activity of the stomach, as required by independent claim 1.

As further indicated by FIG. 7, the delivery of electrical stimulation is repeated until the sensed slow wave rate returns to a desirable value. Blocks 7-8, 7-14, and 7-9 illustrate that stimulation therapy labeled as "normal stimulation therapy" is provided only when the slow wave rate returns to a desirable value. The Examiner characterized this portion of FIG. 7 as determining if normal waves are occurring and, if so, providing stimulation therapy.

However, the "normal stimulation therapy" provided in block 7-9 is not for disrupting normal gastric activity of the stomach, as recited in claim 1. On the contrary, the "normal stimulation therapy" appears to refer to one or more modes of stimulation therapy, rather than delivery of stimulation itself, that a medical device may revert to when the slow wave rate returns to normal. Bourgeois describes examples of "normal stimulation therapy" as an "inhibition mode" in which electrical stimulation is provided only upon the absence of intrinsic slow wave as detected by the device, i.e., stimulation is not provided when a slow wave is detected, or a "demand mode" in which electrical stimulation is provided only when a demand for such stimulation is sensed by the device.[9]

Notably, Bourgeois fails to teach or disclose that "normal stimulation therapy" includes electrical stimulation to disrupt normal gastric activity of the stomach, as set forth in Applicant's claims. Indeed, this would seem to be at odds with the objectives of restoring and maintaining a normal slow wave in the cases of bradygastria and tachygastria.

Consequently, in contrast to the features recited by claim 1, Bourgeois fails to teach or disclose a gastric stimulator that creates electrical stimulation when sensed intrinsic gastric activity is classified as normal, much less stimulation electrodes configured to deliver the electrical stimulation from an implantable gastric stimulator to the stomach wall of the patient when the sensed intrinsic activity is classified as normal, wherein the electrical stimulation is configured to disrupt normal gastric activity of the stomach. To the contrary, Bourgeois appears

[9] *Id.* at col. 9, lines 61-67.

to describe delivery of electrical stimulation when irregular gastric rhythms, such as slow waves at an abnormal rate, are sensed. As previously explained, the apparatus of Bourgeois delivers electrical stimulation that is configured to normalize the slow wave rate, and then revert to a normal stimulation mode after the irregular slow waves have been returned to a normal rate.

Bourgeois provides no teaching that would have suggested any apparent reason for modification to incorporate the features recited by claim 1. As outlined above, Bourgeois generally describes the use of electrical stimulation to return irregular gastric rhythms to normal rates. Accordingly, delivering electrical stimulation to the stomach to disrupt normal gastric activity, as recited by claim 1, would seem to be directly contrary to the teachings of Bourgeois. Instead, it would appear that Bourgeois would suggest maintaining sensed gastric activity that is normal at a normal level instead of delivering electrical stimulation for disrupting normal gastric activity.

For at least these reasons, Bourgeois fails to teach or disclose each and every limitation set forth in independent claim 1. Applicant respectfully requests withdrawal of the rejection.

Independent claim 29 recites a method for gastric stimulation of a patient comprising sensing intrinsic gastric activity on the stomach wall of a patient, classifying the sensed intrinsic electrical gastric activity as normal or abnormal, determining when to apply electrical stimulation to the stomach wall of the patient based upon the classification of the sensed intrinsic gastric activity as normal or abnormal, forming an electrical signal in response to the determining when the sensed intrinsic gastric activity is classified as normal, and applying the electrical signal to disrupt normal gastric activity of the stomach.

The Examiner used the same basis to reject claim 29 as used to reject claim 1. In general, the deficiencies of Bourgeois identified with respect to claim 1 also apply to independent claim 29. For example, claim 29 requires disrupting normal gastric activity of the stomach with an electrical signal. Claim 29 explicitly states that the electrical signal is formed in response to the determining when the sensed intrinsic gastric activity is classified as normal. However, as previously explained, Bourgeois fails to disclose or suggest disrupting normal gastric activity of the stomach with an electrical signal, much less an electrical signal that is formed in response to the determining when the sensed intrinsic gastric activity is classified as normal.

Independent claim 35 recites a system comprising sensing electrodes for sensing intrinsic electrical gastric activity from a stomach wall of a patient, an implantable gastric stimulator coupled to the sensing electrodes, wherein the implantable gastric stimulator receives the sensed intrinsic electrical gastric activity and classifies the activity as normal or abnormal, and wherein the stimulator creates electrical stimulation when the sensed intrinsic electrical gastric activity is classified as normal, and stimulation electrodes for conveying the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient. Per claim 35, the electrical stimulation is configured to disrupt normal gastric activity of the stomach.

The Examiner used the same basis to reject claim 35 as used to reject claims 1 and 29. In general, at least some of the deficiencies of Bourgeois identified with respect to claims 1 and 29 also apply to independent claim 29. Bourgeois fails to disclose or suggest, for example, an electrical stimulation configured to disrupt normal gastric activity of the stomach, much less that the implantable gastric stimulator creates the electrical stimulation when the sensed intrinsic electrical gastric activity is classified as normal.

Independent claim 36 recites a method comprising sensing intrinsic electrical gastric activity from a stomach wall of a patient, classifying the intrinsic electrical gastric activity as normal or abnormal; applying electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as normal, wherein the electrical stimulation is configured to disrupt normal gastric activity of the stomach, and withholding application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal.

In general, at least some of the deficiencies of Bourgeois previously identified with respect to claims 1, 29, and 35 also apply to independent claim 36. For example, Bourgeois fails to teach or disclose applying electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as normal, wherein the electrical stimulation is configured to disrupt normal gastric activity of the stomach, as required by claim 36.

Furthermore, Bourgeois fails to teach or disclose withholding application of electrical stimulation to the patient when the intrinsic electrical gastric activity is classified as abnormal, as required by claim 36.

In the Advisory Action, the Examiner indicated that FIG. 7 of Bourgeois (at step 7-2) describes resetting the loop and withholding stimulation if the rate is outside of selected normal

slow wave band. However, as previously noted, the "Y" and "N" associated with block 7-2 appear to be reversed. For example, the text of the Bourgeois patent refers to proceeding to block 7-3 when the answer to the query in block 7-2 is "yes," and refers to resetting when the answer to the query in block 7-2 is "no".[10] As a result, when viewing Bourgeois in its entirety, one of ordinary skill in the art would recognize that the "Y" and "N" have been transposed with one another in block 7-2 of FIG. 7.

Based on the correct labeling of the labels associated with block 7-2, it is evident that Bourgeois fails to teach or disclose withholding application of electrical stimulation when the intrinsic electrical gastric activity is classified as abnormal. Rather, on the contrary, block 7-2 of FIG. 7 appears to be describing withholding electrical stimulation when a slow wave is inside of a selected normal slow wave band.

With respect to dependent claims 2-5, 7-9, 27-29, and 31, these dependent claims are all either directly or indirectly dependent on independent claim 1 or claim 29. As such, the dependent claims include the limitations of their respective independent claim. For the reasons previously stated, Bourgeois does not teach or disclose all features of independent claims 1 and 29, therefore, does not teach or disclose all features of claims 2-5, 7-9, 27-29, and 31.

For at least these reasons, Bourgeois fails to disclose each and every limitation set forth in claims 1-5, 7-9, 27-29, 31 and 33-36. Accordingly, the final Office Action did not establish a prima facie case for anticipation of Applicant's claims 1-5, 7-9, 27-29, 31 and 33-36 under 35 U.S.C. 102(e). Applicant respectfully requests withdrawal of this rejection.

Claim Rejection Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 6, 11-18 and 30 under 35 U.S.C. 103(a) as being unpatentable over Bourgeois as applied to claims 1 and 7 above, and further in view of Gordon (US 6,895,278). Applicant respectfully traverses the rejection.

The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested an apparent reason to arrive at the claimed invention.

[10] Bourgeois, Col. 9, lines 12-16.

Dependent claims 6, 11–18 and 30 are all either directly or indirectly dependent on independent claim 1 or claim 29. As such, the dependent claims include the limitations of their respective independent claim. For the reasons previously stated, Bourgeois does not disclose or suggest all features of independent claims 1 and 29 and, therefore, does not teach or disclose all features of claims 6, 11–18 and 30. Furthermore, these identified deficiencies are not overcome by the teachings of Gordon.

In addition, Gordon fails to teach or disclose the feature of the stimulator temporarily reverting to a power conserve condition in the absence of a programmable threshold of normal activity, as required by claim 11. While Gordon describes using a programmable calendar 48 in FIG. 3 to provide increased stimulation at certain hours of the day, and decreased stimulation at other hours of the day, the specific times of providing decreased stimulation appear to be preprogrammed times based on when gastric activity is estimated to be less than other times of the day.[11] On the contrary, claim 11 requires that the stimulator revert to a power conservation condition in the absence of a programmable threshold of normal activity, rather than preprogrammed time periods as described by Gordon.

For this additional reason, Bourgeois and Gordon, viewed in combination or individually, fail to teach or disclose the requirements of dependent claim 11, and dependent claims 12-18, which are all either directly or indirectly dependent on claim 11.

Furthermore, Gordon fails to teach or disclose maintaining a history of predecessor electrical events, as required by claim 30. While Gordon describes a device including a memory provided to store data,[12] Gordon makes no mention of maintaining a history of predecessor events, much less predecessor electrical events.

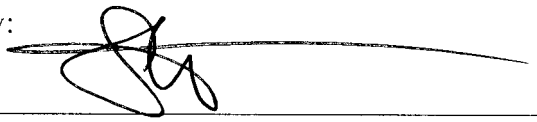
For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 6, 11–18 and 30 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

[11] *See* Gordon, column 10, line 44 to column 11, line 41.
[12] Gordon, column 5, lines 1-3.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 10-15-08

By: 

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